APPENDIX 4: META ANALYSIS - PATIENT OUTCOMES FOLLOWING MOBILE BEARING KNEE REPLACEMENT

Objective

The goals of this meta-analysis were to provide more precise estimates of patient outcomes, and to compare those estimates with the meta-analysis estimates provided by Callahan et al. concerning tricompartmental fixed bearing knee replacement.

Data Sources

English-language articles identified through a computerized MEDLINE literature search and bibliography review.

Study Selection

Studies were included if they enrolled 10 or more patients at the time of initial knee replacement and measured patient outcomes using a global knee-rating scale.

Data Extraction

Each study was subjected to a qualitative assessment and abstraction of patient characteristics, PCL treatment, and outcomes.

Data Synthesis

A total of 21 studies reporting patient outcomes on 22 cohorts satisfied inclusion criteria. The total number of enrolled knees was 2870 (2490 patients) with a mean enrolment of 138 patients. The mean follow-up was 6.0 years. The mean patient age was 66.1 years, 62.3% of patients were women, 82.3% had osteoarthritis, and 13% underwent bilateral replacement. The raw, weighted mean percentage of patients with good or excellent outcomes following mobile bearing knee replacement was 90.3% (95% confidence limits 72% and 96%). The weighted mean percentage of patients with good to excellent outcomes following fixed bearing total knee replacement reported by Callahan et al. was 89.3%. Results were also similar comparing percent improvement in global rating scale score: current study 91.4% (95% confidence limits 53% and 127%) and Callahan et al. 100%, respectively.

Conclusions

The average mobile bearing knee replacement was a safe and effective procedure for the patients reported in these studies. Furthermore, these mobile bearing meta-analysis estimates are similar to the fixed bearing meta-analysis estimates reported by Callahan et al. (Global rating scale score improvement was 100%, and patients reporting good or excellent outcomes was 89.3%).

INTRODUCTION

Mobile bearing knee prostheses were designed for two main reasons[5, 112, 127]. The first was to reduce polyethylene contact stresses, potentially decreasing the fatigue failure associated with polyethylene failure in total knee arthroplasty. The second reason was to more fully recreate normal knee kinematics. All mobile bearing devices can be described as involving a moving polyethylene bearing separating the femoral condyle from the tibial tray[181]. Most orthopaedic manufacturers have developed or are currently developing a mobile bearing prosthesis[181].

Theoretically, improved congruency and decreased axial constraint of a mobile bearing device should lead to less polyethylene wear and reduced loosening torque applied at the prosthesis-bone interface[190]. Other possible benefits include improved patellofemoral and tibiofemoral biomechanics with increased maximal flexion.

Good range of motion and stability have been achieved with fixed bearing TKAs, however, component loosening remains their most common long-term problem[92, 140]. Although results have been promising using fixed bearing TKAs, young, active patients have been considered as a relative contraindication[73]. Mobile bearing knee replacement may offer a solution to these patients by providing physiologic mobility and, at the same time, eliminate unnecessary constraint forces.

The goal of this meta-analysis was to perform a systematic literature review to describe patient outcomes following mobile bearing knee replacement, and to examine the impact of prosthetic type and PCL treatment on these outcomes. The majority of studies addressing outcomes following mobile knee replacement use an observational design rather than an experimental study design. For this reason, the methods utilized for this systematic literature review were based on a previously published study[30].

METHODS

Literature Search

A computerized literature search was performed using MEDLINE to identify all citations concerning mobile bearing knee surgery articles published from 1977 (the time at which mobile bearing knees were introduced) through 2002. The literature search was initiated on April 2, 2002 and was closed on July 2, 2002. A copy of the article was obtained for each identified English-language citation except those references that included the Medical Subject Headings (MeSH) terms “amputation”, “animal”, “bone neoplasm”, or “case report”. Citations were also added by examining reference lists retrieved from each article.

A multi-staged assessment to determine which articles that contained data that could address the study questions was then performed. In the first stage assessment, the number of patients enrolled and whether the article reported on any postoperative

outcomes was determined. Case reports or studies that enrolled fewer than 10 subjects were excluded. The interest of this study was on primary knee replacement, therefore the second stage of the assessment excluded those studies that reported on procedures other than knee replacement or did not report on relevant postoperative outcomes. This was defined as any postoperative data on mortality, function, pain, or complication rate. The third stage assessment excluded those studies that did not use a global rating scale to describe patient outcomes. A global knee rating scale was defined as an instrument that measured patient outcomes in the domains of pain, function, and range of motion and combined these domains in a summary scale[30]. The global rating score from each study was the effect size statistic used to allow comparisons across studies. Studies that met the criteria of these three filters were included for the mobile bearing knee meta-analysis.

Mobile bearing knee designs in the meta-analysis included: cemented and uncemented designs; unicompartmental, bicompartmental, and tricompartmental replacement; multidirectional platform, rotating platform, and meniscal bearing articulation; PCL-sacrificing and PCL-sparing designs. The mobile bearing classification was defined and all inclusive regardless of cement technique, number of compartments replaced, mobile bearing type, and PCL treatment. Callahan et al.[30] included both cemented and uncemented knees, as well as, all PCL treatments in the literature search and the current study remained consistent with this method. In order to include a sufficient number of mobile bearing knee articles for the meta-analysis, the bearing type, and number of compartments replaced was not used to exclude articles.

Qualitative Assessment

All articles that met the inclusion criteria were subjected to a qualitative assessment[30]. Using the "Methods" section from each study, the following questions were answered: 1) Was the study design a randomized clinical trial, prospective cohort, historical cohort, other, or uncertain? 2) Was the outcome assessment blinded, unblinded but conducted by an independent assessor, unblinded and not independent, other, or uncertain? 3) Was the sample population described in sufficient detail to know to whom the results apply? 4) Was the sample population described in sufficient detail to understand the effects of confounding medical conditions?

Data Abstraction

The data abstraction was completed by a research professional who was educated in the data abstraction requirements. Only variables that were consistently reported across the majority of studies could be analyzed. Difficulties in abstracting data resulted from two types of missing data. The first came when authors did not mention a variable of interest in a study. The data abstractor could not determine if the variable was absent from the study or if it was not reported. The second difficulty arose when the variable of interest was mentioned as part of a subset of enrolled patients, but were not mentioned in number or stratified in the results.

Reporting style was also problematic. Authors reported data using the patient or knee as the unit of analysis. The number of "cases" or number of knees was used for this meta-analysis. The second problem involved the author's choice of global knee-rating system and the method of reporting used for the scores. To allow comparison across studies, the mean preoperative and postoperative global knee-rating scale score using a 100-point scale was used.

The reporting of complications also showed variability. To allow comparison across studies, perioperative complication data were not collected. Complication data that was collected included the following categories: knees with any complication, knees with any revision, knees with revision for mechanical failure, knees with revision for aseptic loosening, and knees with revision for septic loosening.

The anatomic portion of this classification scheme identified the prostheses by treatment of the posterior cruciate ligament (sparing, sacrificing, or both (sparing/sacrificing of PCL used in same study). When an article reported across more than one anatomic classification and provided patient characteristics for each group, the data were treated as two separate articles. When an article reported data across more than one classification but did not provide patient characteristics for each group, the study was considered as a mixed group of prostheses.

Statistical Methods

Eight studies of the 22 included for analysis contained outcome measures of interest (% good to excellent and mean percent improvement in global rating score). As a method of sensitivity analysis, imputation methods utilizing the 8 studies that contained data on both outcome variables of interest were used to predict the values of studies with missing data to explore its impact on the estimates of patient outcomes. However, final analysis were restricted to the actual data extracted from the literature. For reporting the percent of patients with good or excellent global outcomes rating scores, imputation was performed for 5 studies (16 studies reported the value in the article, 1 was missing). For the outcome measure reporting improvement in global rating scale, imputation was performed for 8 studies (13 studies reported the value in the article, 1 was missing). Least squares models were developed for each of the two outcomes which fit the data well (% good to excellent R^2= 0.82; improvement in global rating scale R^2= 0.84). Table 11 in Appendix 4 shows the original or imputed data for the outcome variables of interest for each mobile bearing knee study.

A bootstrap re-sampling procedure was used to estimate the confidence limits for outcomes using a paired re-sampling procedure. Within each PCL treatment group, an outcome and the corresponding number of knees (pair) were chosen at random and with replacement. This procedure was repeated 16 times for % good to excellent and 13 times for % improvement. Weighted least squares (WLS) estimation was then performed on this "bootstrapped" data set and was repeated 1,000 times. Two-sided empirical ninety-five percent confidence intervals for each outcome were generated from the distribution of WLS estimates.

Data Analyses

Data were summarized across studies within anatomic classifications and for the entire group of articles by providing means and ranges for each of the abstracted variables. Individual studies varied in the number of enrolled patients therefore, each of these means was weighted by the number of knees operated on. Outcome variables of interest included: postoperative mean patient global rating score, mean difference between preoperative and postoperative global rating scale, mean percentage of patients with good to excellent outcomes, mean percentage of knees with any complication, and mean percentage of knees with any revision.

RESULTS

Literature Description

A total of 274 articles (198 through Medline search and 76 through bibliographical review) were identified in the literature search: 29 were non-English language, 13 articles reported fewer than 10 patients, and 106 articles contained no original patient data (i.e., reviews, editorials, or biomechanical studies). The remaining 126 articles proceeded to the second–stage assessment. Among these studies, 72 reported on knee procedures other than knee replacement, and 10 reported no patient outcomes pertinent to the study specific questions (usually involved radiographic outcomes). Of the remaining 44 articles that proceeded to the third and final assessment, 23 were eliminated because they did not report patient outcomes using a global knee-rating scale. This left 21 studies that passed through all three filters and reported on patient outcomes following mobile bearing knee replacement.

These 21 articles were published from 1987 through 2002, and 71.4% were published from 1999 through 2002. The articles were published in 11 different journals, and 50% appeared in one of 3 journals (18.2% in *Clinical Orthopaedics*, 18.2% in *Journal of Arthroplasty*, and 13.6% in *The Knee*).

One of the 21 studies reported stratified results across two different prosthetic classifications for a total of 22 patient cohorts. There were 12 studies that used meniscal bearings, 8 that used rotating platforms, and 2 that used both. Five studies reported unicompartmental replacement, 16 reported total knee replacement, and 1 study reported combining unicompartmental and tricompartmental replacements. Of these 22 studies, 14 (63.6%) used a posterior cruciate ligament-sparing prosthesis, 5 (22.7%) used a posterior cruciate ligament-sacrificing prosthesis, and 3 (13.6%) reported using a combination of the two PCL treatments.

Qualitative Assessment

Table 12 in Appendix 4 shows the study characteristics across the three anatomic classifications of prostheses. The total number of knees summed across 22 studies was 2870. The studies reported outcomes on a mean of 130.5 knees with a mean follow-up of 6 years, and 5.8% of knees were lost to follow-up for any reason.

Only one study (5%) used a clinical trial design, 5 (23%) were prospective cohorts, and 13 (59%) were historical cohort studies as judged by the reviewer. The study design in the remaining 3 studies (14%) could not be determined. No study reported that the person assessing patient outcomes was blinded to the patient's treatment status. There were 4 studies (18%) that reported using unblinded but independent assessors, and 6 studies (27%) reported that the assessor was unblinded and not independent. For the majority of studies however, 55% of them could not be assessed for the method of outcome assessment. With regard to whether the sample population was described in sufficient detail to know to whom the results apply, this judgment was yes or probably for 63% of studies, and for the description of co-morbid medical conditions, this judgment was yes or probably for 59% of studies.

Summary of Findings

Table 13 in Appendix 4 displays the patient characteristics that are based on Callahan et al. (1994). The weighted mean patient age across all studies was 66.5 years, and 62.8% of enrolled patients were women. Osteoarthritis was the underlying pathology in a majority of knees (80.9%).

Table 14 in Appendix 4 displays the difference between the preoperative and postoperative global rating knee scale with the average being 44.2 points. The range of the percentage of patients with good or excellent outcomes following mobile bearing knee replacement was 35% to 100%.

Table 15 in Appendix shows the results for the percent of patients reporting good or excellent results and the pre to post improvement in the global rating knee scale. The weighted mean using only the studies reporting good or excellent outcome ratings was 90.3%. The weighted mean using the reporting studies and the imputed good or excellent outcome ratings was 92.6%. The pre to post weighted mean improvement in the global rating knee scale percentage was 91.4% for those studies reporting the value in the literature and 73.7% combining the reported literature value and imputed values.

Most studies mentioned the rate and reason for knee revision. Reason for revision included mechanical failure, aseptic loosening, septic loosening, and bearing breakage, dislocation or subluxation (a classification unique to mobile bearing knees). Table 16 in Appendix 4 displays the postoperative complications that led to subsequent revision. The overall rate of revision was 6.4% with a mean follow-up of 6 years.

COMMENT

This study summarizes the results of a systemic review of the literature reporting on patient outcomes following mobile bearing knee replacement. The goals of this meta-analysis were to provide more precise estimates of patient outcomes, and to compare those estimates with the meta-analysis estimates provided by Callahan et al. concerning tricompartmental fixed bearing knee replacement.

Table 17 in Appendix 4 shows the comparison of outcome values between mobile vs. fixed bearing meta-analysis results. Callahan et al. reported on far more knees (9879 vs. 2870) and cohorts (154 vs. 22) than the current study. The raw, weighted mean percentage of patients with good or excellent outcomes following mobile bearing knee replacement was 90.3%. The weighted mean percentage of patients with good to excellent outcomes following fixed bearing total knee replacement reported by Callahan et al. was 89.3%. Results were also very similar comparing % improvement in global rating scale score: Callahan et al. 100%, current study 91.4%. Comparing the revision rate of mobile bearing studies against fixed bearing studies initially revealed a large difference: 3.8% vs. 6.4%. But two of the mobile bearing studies had revision rates of 30%. These two studies reported on the Oxford unicompartmental phase I knee replacement and the Accord total knee replacement. Both of these designs are no longer used. After exclusion of these two studies the revision rate comparison is more similar; 3.8% for fixed bearing knees and 5.1% for mobile bearing knees.

In conclusion, these meta-analyses show that mobile bearing knees function similarly when compared to fixed bearing knees.

Table 11. Values for outcome variables of interest from the mobile bearing knee literature.

Study	% Good to Excellent	% improvement in GRS
1	---	---
2	93.8	59.0†
3*	99.0	91.0
4	97.2†	47.0
5*	89.0	57.0
6	35.0	0.0†
7	83.7	44.0†
8	98.5†	221.0
9	100.0†	140.0
10*	97.4	68.0
11	97.5	67.0†
12	100.0†	142.0
13*	90.0	47.0
14	88.0	37.0†
15*	93.3	59.0
16	95.0	69.0†
17	76.9	29.0†
18	100.0†	111.0
19*	85.0	49.0
20*	97.0	41.0
21	89.0	48.0†
22*	100.0	63.0

* Studies that were included in the least squares model to impute missing values.
† Imputed value: Weighted least squares regression- weighted by number of knees operated on

Table 12. Study Characteristics by Anatomic Classification of Prosthesis

Anatomic Classification	Total No. of Studies	No. of Knees, Mean (Range)	Total No. of Knees	Years of Follow-up, Mean (Range)	Patient-Years of Follow-up, Mean (Range)	Percentage of Knees Lost to Follow-up Mean (Range)
PCL sparing*	14	133.3 (21-473)	1866	5.1 (2.8-7.8)	27.4 (7-101)	3.8 (0-11)
PCL sacrificing†	5	117.4 (44-233)	587	8.4 (5.3-12.8)	13.2 (7-18)	11.4 (5-21)
PCL sparing & sacrificing combined (mixed prostheses)‡	3	139.0 (104-208)	417	6.3 (4.2-9.4)	22.4 (20-25)	5.5 (3-8)
Total	22	130.5 (21-473)	2870	6.0 (2.8-12.8)	23.5 (7-101)	5.8 (0-21)

* Individual prosthesis names include Oxford, Self Aligning I, Minns, Rotaglide, and LCS Meniscal Bearing
† Individual prosthesis names include LCS Rotating Platform and Accord
‡ Individual prosthesis names include LCS system (Did not specify PCL treatment, or used both sparing and sacrificing replacements)

Table 13. Patient characteristics by anatomic classification of prostheses.

	PCL Sparing** (n=14)†	PCL Sacrificing** (n=5)†	Mixed Prostheses (n=3)†	Total (95% CI)‡ (n=22)†
Patient age*, y	67.6 (60-71)	65.0 (56-68)	63.5 (60-68)	66.5 (66.3-66.6)
Female*, %	60.7 (2-79)	64.6 (54-74)	69.1 (59.6-84)	62.8 (62.2-63.4)
Patients with OA*, %	84.6 (57-100)	75.8 (66-95)	72.5 (57-92)	80.9 (80.4-81.5)
Patients with RA*, %	12.1 (0-43)	13.3 (5-21)	15.3 (8-19)	12.9 (12.5-13.2)

* Mean (range). Weighted by the number of knees operated on for each study.
**PCL indicates posterior cruciate ligament.
† Number of studies
‡ CI indicates confidence interval

Table 14. Patient outcomes by anatomic classification of prostheses

	PCL Sparing** (n=14)†	PCL Sacrificing** (n=5)†	Mixed Prosthesis (n=3)†	Total (95% CI)‡ (n=22)†
No. of Knees	133.3 (21-473)	117.4 (44-233)	139.0 (104-208)	130.5 (87.7-173.2)
Preoperative global rating scale*	42.1 (29-66)	52.2 (45-61)	48.5 (44-53)	45.5 (44.9-46.0)
Postoperative global rating scale*	89.5 (80-94)	83.5 (60-91)	88.6 (84-93)	87.8 (87.6-88.1)
Difference between preoperative and postoperative global rating score*	49.0 (27-64)	34.6 (27-41)	40.1 (31-49)	44.2 (43.6-44.8)

* Mean (range). Weighted by the number of knees operated on for each study.
**PCL indicates posterior cruciate ligament.
† Number of studies
‡ CI indicates confidence interval

Table 15. Patient outcomes involving imputation by anatomic classification of prostheses

Patient Improvement %	PCL Sparing** (n=14)†	PCL Sacrificing** (n=5)†	Mixed Prosthesis (n=3)†	Total (n=22)†
Raw data*, %	128.0	67.7	87.0	91.4
95% CI‡	(42.8, 220.7)	(47.4, 91.1)	(59.1, 111.4)	(53.1, 127.9)
Raw and imputed data*, %	98.8	54.5	71.9	73.7
Patients with good or excellent outcome rating %				
Raw data*, %	92.1	85.5	93.6	90.3
95% CI‡	(85.3, 96.0)	(35.0, 100)	(93.3, 93.8)	(72.5, 96.5)
Raw and imputed data*, %	94.8	87.9	95.2	92.6

* Weighted Least Squares Regression- Weighted by number of knees operated on.
**PCL indicates posterior cruciate ligament.
† Number of studies
‡ CI indicates confidence interval (Based on the 2.5th and 97.5th percentiles of the distribution of (2-stage) bootstrap estimates)

Table 16. Postoperative complications by anatomic classification of prostheses

	PCL Sparing (n=14)†**	**PCL Sacrificing** (n=5)†**	**Mixed Prosthesis (n=3)†**	**Total (95% CI)‡ (n=22)†**
No. of Knees	133.3 (21-473)	117.4 (44-233)	139.0 (104-208)	130.5 (87.7-173.2)
Knees with any complication*, %	5.0 (1-27)	14.1 (0-55)	46.9 (8-86)	9.9 (9.2-10.7)
Knees with manipulation under anaesthesia*, %	0.5 (0-5)	1.3 (0-3)	19.1 (0-38)	3.0 (2.6-3.5)
Knees with any revision*, %	5.6 (0-30)	9.2 (0-34)	6.2 (6-7)	6.4 (6.2-6.6)
Knees with revision for mechanical failure*, %	1.5 (0-5)	5.2 (0-14)	2.4 (1-4)	2.3 (2.1-2.4)
Knees with revision for aseptic loosening*, %	2.7 (0-24)	2.6 (0-11)	1.4 (0-3)	2.4 (2.2-2.6)
Knees with revision for septic failure*, %	0.7 (0-1)	1.4 (1-2)	2.3 (0-5)	1.2 (1.1-1.2)
Knees with revision for bearing dislocation, breakage, or subluxation*, %	0.0 (0-0)	2.8 (0-11)	1.2 (0-3)	2.2 (2.1-2.3)

* Mean (range). Weighted by the number of knees operated on for each study.
**PCL indicates posterior cruciate ligament.
† Number of studies
‡ CI indicates confidence interval

Table 17. Comparison of mobile vs. fixed meta-analysis results

	Mobile bearing knee outcome result (Current study)	Mobile bearing knee outcome result excluding Oxford phase I and Accord Knee	Tricompartmental fixed bearing knee outcome result (Callahan et al. 1994)
No. of knees	2870	2729	9879
Weighted mean years of follow-up	6.0	6.4	4.1
No. of cohorts analysed	22	20	154
Weighted mean % good or excellent	90.3*	93.4*	89.3
% improvement in global rating scale	91.4*	91.4*	100
Weighted mean postoperative global rating scale score	87.8	89.0	86.6
Weighted mean % knees with any revision	6.4	5.1	3.8

* Raw data